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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference AFB/P8944WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB 03/01875	International filing date (day/month/year) 01.05.2003	Priority date (day/month/year) 01.05.2002
International Patent Classification (IPC) or both national classification and IPC A61M16/00		
Applicant AIR PRODUCTS AND CHEMICAL, INC. et al.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input checked="" type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 27.11.2003	Date of completion of this report 18.06.2004	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Borowski, A Telephone No. +49 89 2399-2758 	

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I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-19 as originally filed

Claims, Numbers

1-24 as originally filed

Drawings, Sheets

1-4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 16-24

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 16-24

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☒ complied with.

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☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-15
	No: Claims	
Inventive step (IS)	Yes: Claims	8,10,11,13-15
	No: Claims	1-7,9,12
Industrial applicability (IA)	Yes: Claims	1-15
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 16-24 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT: a method of providing a medical device (and further a patient - see fig. 1) with a medical gas mixture. Claim 16 discloses a method of providing a medical device with a medical gas mixture and as such could also be seen as non-medical method, but considering claim 17 which is dependent on claim 16 and discloses operating an artificial ventilator (feature of claim 13) it becomes clear, that claim 16 constitutes a step in a method for treatment by therapy.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1: US-A-6 131 571 (GRAVENSTEIN JOACHIM S ET AL) 17 October 2000 (2000-10-17)
- D2: EP-A-0 861 672 (PANINA ELENA VLADIMIROVNA) 2 September 1998 (1998-09-02)
- D3: EP-A-0 745 405 (SIEMENS ELEMA AB) 4 December 1996 (1996-12-04)
- D4: SU-A-1 188 638 (DYACHENKO MIKHAIL A) 30 October 1985 (1985-10-30)

V.1 Claims 1-7, 9 and 12 of the present application do not meet the requirements for inventive step (Article 33(3) PCT).

Document D1 is considered to represent the most relevant state of the art to the subject-matter of claim 1 and discloses:

An apparatus for providing and circulating to a medical device a medical gas mixture comprising at least two components, said apparatus comprising:

-) a main gas circuit for recirculating the medical gas mixture and comprising:
 - a constant speed circulation pump for pumping gas through the main circuit and increasing the gas pressure from a lower pressure to a higher pressure (Column 7, Lines 50-52; Fig. 2 (36)),
 - a pressure maintaining valve downstream of the pump, dividing the

main circuit into a higher pressure section and a lower pressure section (Fig. 2 (132)) (the valve has a different task in the system disclosed by D1, but is suitable for maintaining the pressure),

- a medical gas outlet in the higher pressure section (Fig. 2 (14)),
 - a spent gas inlet (Fig. 2 (14)),
 - a first feed gas supply inlet (Fig. 2 (200)),
 - a second feed gas supply inlet (Fig. 2 (202)) downstream of the gas outlet and upstream of the pressure reduction valve,
 - concentration determining means suitable for measuring the concentration of at least one component of the recirculating medical gas mixture (Fig. 2 (120)) (as the recirculated gas enters the circulation loop (Fig. 2 (12)) through the Y-piece and the endotracheal tube (Fig. 2 (14, 16)) and generating a signal (Fig. 2 (124)) indicative of said concentration,
 - circuit volume regulating means (Fig. 2 (212)) for varying the volume of the main circuit at a location in the lower pressure section for maintaining a predetermined gas flow to the pump and generating a signal (Fig. 2 (226)) indicative of said volume, and
 - means for venting gas from the main circuit (Fig. 2 (130)(150));
-) a first feed gas supply conduit (Fig. 2 (200)) for supply to the first feed gas inlet of a first feed gas of predetermined composition;
 -) first feed gas supply flow control means for controlling the flow of first feed gas through the first gas supply conduit in response (among others, not exclusively) to the signal from the concentration determining means to maintain constant the medical gas composition at the pump inlet (Column 13, Lines 38-44);
 -) a second feed gas supply conduit (Fig. 2 (202)) for supply to the second feed gas inlet of a second feed gas of predetermined composition different from the first feed gas;
 -) second feed gas supply flow control means for controlling the flow of second feed gas through the second gas supply conduit in response (among others, not exclusively) to the signal from the circuit volume regulating means to maintain constant the recirculating medical gas composition (Column 21, Lines 32-44); and
 -) a medical device supply circuit (Fig. 2 (14)(16)) for connecting the medical device to the main circuit to receive a portion of the medical gas from the

medical gas outlet thereof and to return spent gas to the spent gas inlet thereof.

The device defined by common technical features therefore differs from the device known from document D1 in that:

- it comprises a purification means for removing contaminants from the spent gas,
- the spent gas inlet is located in the low-pressure section,
- the medical device supply circuit comprises a flow control means. for controlling flow of the medical gas to the medical device.

There are two separate problems to be solved by the differentiating features, which may therefore be regarded as:

- how to protect the gas circuit against impurities and microflora coming from exhaled air,
- how to ensure a constant flow of gas through the medical device, and
- how to improve the supply of the medical device with the medical gas.

However, these features have already been employed for the same purposes in a similar device, see document D2: Column 4, Lines 6-26, Figure (26) (spent gas inlet in the low-pressure section), Column 5, Lines 20-22, Figure (25) (purification means in the spent gas inlet) and Figure (17, 18). It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a device according to document D1, thereby arriving at a device defined by claim 1.

Dependent claims 2-7, 9 and 12 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, the reasons being as follows:

- gas supply either in the higher (claim 2) or in the lower pressure section is a matter of normal design procedure, see for example document D3, column 5, lines 19-34 and fig. 1 (10, 12, 14);
- all features of dependent claims 3-6 are already known from document D1, see for example fig. 2 (182,188,194) for spill valve of claim 3, fig. 2 (210) for expansion bellows of claim 4, and column 13, lines 33-44 for measuring oxygen concentration of claim 6;

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- supply of third gas (claim 7) is known from document D2, see figure (3, 4, 6).
- use of an ultrasonic xenon analyser (claim 9) is a matter of normal design procedure, see for example document D4 column 1, lines 1-5.
- a medical device system comprising a medical device connected to the medical device supply circuit (claim 12) is known from a combination of documents D1 and D2, where the medical device is an endotracheal tube (D1: Fig.2 (16)) or a breathing mask (D2: Figure (19)).

V.2 The terms "a relatively high gain", "a relatively low gain", "relatively quick flow rate" and "relatively slow flow rate" used in claim 5 are vague and unclear and leave the reader in doubt as to the meaning of the technical features to which they refer, thereby rendering the definition of the subject-matter of said claim unclear (Article 6 PCT). The claim does not define in relation to which object (parameter) the gain is high/low and the flow rate is quick/slow.

V.3 The additional features of dependent claims 8, 10, 11 and 13-15 are neither known from, nor rendered obvious by the available prior art. Said features improve the applicability of gas recirculating systems (claim 8) or enable an effective recovery of high value gases (claims 10 and 11). Known systems (e.g. D1 or D2) are directed to provide patients directly with a medical gas mixture, the gas mixture being recirculated afterwards, i.e. they are connected to a patient through a breathing mask or a tracheal tube and support the patient with artificial ventilation with variable pressure (aspirations and expirations), whereby the systems of claims 13-15 provide an artificial ventilator (comprised in the system and being responsible for artificial ventilation) with the mixture of gases with constant pressure thereby enabling more sophisticated artificial ventilation procedures.

V.4 The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).